

REMARKS

This responds to the Office Action mailed on October 29, 2003. Claims 69, 70 and 71 are amended. No claims are cancelled or added. As a result, claims 41-75 remain pending in this patent application.

§102 Rejection of the Claims

1. Claims 48, 49, 63 and 66 were rejected under 35 U.S.C. § 102(b) for anticipation by Verboven-Nelissen (U.S. Patent No. 5,720,768). Applicant respectfully traverses.

Applicant cannot find any disclosure in the cited portions of Verboven-Nelissen of delivering a pacing stimulation pulse between right and left ventricular electrodes, as recited or incorporated in these claims. Instead, the cited portions of Verboven-Nelissen apparently refer only to sensing between right and left ventricular electrodes. (*See* Verboven-Nelissen col. 5, lines 28-32.) Accordingly, Applicant respectfully requests withdrawal of this basis of rejection of these claims.

2. Claims 69 and 70 were rejected under 35 U.S.C. § 102(e) for anticipation by Schloss (U.S. Patent No. 6,539,260). Applicant respectfully traverses.

As an initial note, Applicant does not admit that Schloss is prior art and reserves the right to swear behind it at a later date provided under 37 C.F.R. § 1.131. Nevertheless, Applicant believes that these claims are distinct over Schloss for the reasons stated below.

Claims 69 and 70 were amended to correct a typographical error. Support for the amendments is found generally throughout the specification. (*See, e.g.,* Application at page 22 lines 24-29.) Applicant cannot find any disclosure in Schloss of disposing an anodic first electrode within a ventricle at its apex; disposing a cathodic second electrode within the ventricle more proximally than the first electrode; and delivering a pacing pulse between the anodic apical first electrode and the cathodic proximal second electrode, as presently recited or incorporated into claims 69 and 70. Instead, Schloss apparently discloses only bipolar pacing with a cathodic tip electrode at the ventricular apex and an anodic electrode located more proximally within the ventricle. (*See* Schloss at column 2, lines 13 – 18.) Accordingly, Applicant respectfully requests withdrawal of this basis of rejection of these claims.

§103 Rejection of the Claims

1. Claims 55 and 56 were rejected under 35 U.S.C. § 103(a) for obviousness over a single reference, i.e., Helland (U.S. Patent No. 5,431,681). Applicant respectfully traverses this single-reference obviousness rejection.

To establish *prima facie* obviousness, all the claim limitations must be taught or suggested by the prior art. However, Applicant cannot find in the cited portions of Helland any disclosure, teaching, or suggestion of delivering a pacing energy level pulse from a first ventricular defibrillation electrode as a cathode to a first ventricular pacing/sensing electrode as an anode, as recited in claim 55, or where the anode is located at the ventricular apex, as recited in claim 56. In fact, the Office Action admits that Helland only discloses a tip electrode acting as a cathode and a defibrillation electrode acting as an anode. (*See* Office Action at 3.) However, the Office Action asserts that this difference between the present claims and Helland constitutes “a mere reversal of the essential working parts of the device [that] involves only routine skill in the art.” (*See id.*) In making this assertion that mere reversal of parts will not support patentability, however, the Office Action relies on *In Re Einstein*, 46 F.2d 373, 8 U.S.P.Q. 167 (CCPA 1931). But the U.S. Court of Customs and Patent Appeals provided a more clear statement of this rule when it discussed the *In Re Einstein* case in *In re Van Yzeren*, 185 F.2d 705, 88 U.S.P.Q. 90 (CCPA 1950), in which the Court clarified that it is a reversal of parts that is not accompanied by a change of function or by a new or unobvious result that cannot support patentability.

In the present case, however, using the defibrillation electrode as a cathode and a pacing tip electrode as an anode creates a clinically significant different result—it switches the direction of the pacing vector, which will affect how myocardial cells respond to a stimulating pacing pulse. This provides the physician with an additional option for tailoring the therapy to meet a specific patient’s needs for pacing therapy while expending as little energy as needed, thereby extending the useful life of the implanted device before replacement is necessary. (*See, e.g.*, Application at 23.) This, in turn, will lower health care costs, which benefits both the patient and society, since health care costs are typically amortized over a large population. Therefore, Applicant respectfully submits that because the claim language delineates a configuration with a

clinically significant impact, it does not constitute a mere reversal of parts without change in function or result, and therefore is patentable over Helland.

Also, to establish *prima facie* obviousness, the prior art must suggest the desirability of the claimed invention. The mere fact that the prior art could be modified to provide the claimed invention is not sufficient to establish obviousness, there must be a motivation (e.g., a teaching, suggestion, or incentive) in the prior art to make such modification. Applicant cannot find in the cited portions of Helland or in the cited portions of any of the cited art, any teaching, suggestion, or incentive to deliver a pace from a defibrillation electrode as a cathode to a pacing/sensing electrode as an anode, as recited in claim 55. To the extent that such a motivation is based on the Examiner's personal knowledge, Applicant objects to the Examiner's reliance on Official Notice and respectfully requests a reference supporting such a teaching or suggestion. See MPEP § 2144.03.

Evidence showing there was no reasonable expectation of success may also support a conclusion of non-obviousness. For over twenty-five years of pacing, the art has followed the conventional teaching of placing the more negative electrode, the cathode, towards the apex of the ventricle and placing the more positive electrode, the anode, proximal from the cathode because it was thought that doing so obtained the benefit of heart muscle capture. Consequently, Applicant submits that following the conventional method over a long period of time provides evidence that there was no reasonable expectation of success in reversing the order of cathode/anode as recited in claims 55 and 56. Thus, applicant respectfully submits that the arrangement of cathode and anode using a defibrillation electrode is not obvious over the cited art.

Accordingly, Applicant respectfully requests withdrawal of this basis of rejection and allowance of these claims.

2. Claims 50 and 67 were rejected under 35 U.S.C. § 103(a) for obviousness over Verboven-Nelissen (U.S. Patent No. 5,720,768).

Applicant respectfully traverses. Claims 50 and 67 incorporate all the language of claims 48 and 53, respectively. However, as discussed above with respect to the § 102 rejection of claims 48 and 63, Applicant cannot find any disclosure, teaching, or suggestion of delivering a pacing pulse between an electrode in the left ventricle and an electrode in a right ventricle.

Because all elements are not present in the single cited reference, Applicant respectfully submits that no *prima facie* case of obviousness exists for these claims. Accordingly, Applicant respectfully requests withdrawal of this basis of rejection of these claims.

3. Claims 51-54, 64-65 and 68 were rejected under 35 USC § 103(a) for obviousness over Verboven-Nelissen (U.S. Patent No. 5,720,768) in view of Schloss (U.S. Patent No. 6,539,260). Applicant respectfully traverses.

Claims 51-54 depend from and incorporate the language of claim 48. Claims 64 - 65 and 68 depend from and incorporate the language of claim 63. However, Applicant cannot find any disclosure, teaching, or suggestion in Verboven-Nelissen and/or Schloss of delivering a pacing pulse between an electrode in the left ventricle and an electrode in a right ventricle, as discussed above with respect to the § 102 rejection of claims 48 and 63. Accordingly, Applicant respectfully requests withdrawal of this basis of rejection of these claims.

4. Claims 41, 42, 47 and 57-60 were rejected under 35 USC § 103(a) as being unpatentable over Schloss (U.S. Patent No. 6,539,260). Applicant respectfully traverses this single-reference obviousness rejection.

To establish *prima facie* obviousness, all claim elements must be taught or suggested in the prior art. However, Applicant cannot find in the cited portions of Schloss any disclosure, teaching, or suggestion of among other things, delivering a pacing pulse from the left ventricle to the right atrium, as recited or incorporated in claims 41, 42, 47 and 57-60. Applicant cannot find in Schloss any disclosure, teaching, or suggestion of a first pacing pulse vector programmable between (1) at least a first left ventricular electrode and a second left ventricular electrode in a left ventricular region and (2) an electrode in the right atrial region, as recited in claim 41.

Moreover, to establish proper *prima facie* obviousness, the prior art also must suggest the desirability of the claimed invention. The mere fact that the prior art could be modified to provide the claimed invention is not sufficient to establish obviousness, there must be a motivation (e.g., a teaching, suggestion, or incentive) in the prior art to make such modification. However, Applicant is unable to find in Schloss any disclosure, teaching, suggestion, or incentive of pacing from the left ventricle region to the right atrium region. To the extent that such a motivation is based on the Examiner's personal knowledge, Applicant objects to the

Examiner's reliance on Official Notice and respectfully requests a reference supporting such a teaching or suggestion. See MPEP § 2144.03.

The Office Action also stated that the Applicant does not disclose the criticality of pacing between an electrode in the right atrium and an electrode in the left ventricle. (*See* Office Action at 5.) Applicant does not admit that this a critical element. Rather, Applicant respectfully submits that this is only one element of the claimed invention. However, Applicant does traverse any assertion that pacing between the right atrium and the left ventricle is a mere design consideration. (*See id.*) The choice of right atrial and left ventricular electrodes, for delivering a pacing pulse therebetween, defines a pacing vector. The pacing vector determines which cardiac tissue mass the stimulating energy will be focused upon. This has clinical significance because it will affect which myocardial cells respond to a stimulating pacing pulse. It provides the physician with an additional option for tailoring the therapy to meet a specific patient's needs for pacing therapy while expending as little energy as needed, thereby extending the useful life of the implanted device before replacement is necessary. (*See, e.g.*, Application at 23.) This, in turn, will lower health care costs, which benefits both the patient and society, since health care costs are typically amortized over a large population. Therefore, Applicant respectfully submits that because the claim language delineates a configuration with a clinically significant impact, it does not constitute a mere design consideration, and therefore is patentable over Schloss. Accordingly, Applicant respectfully requests withdrawal of this basis of rejection of claims 41, 42, 47 and 57-60.

5. Claims 43-46, 61-62 and 71-75 were rejected under 35 USC § 103(a) for obviousness over Schloss (U.S. Patent No. 6,539,260) in view of Verboven-Nelissen (U.S. Patent No. 5,720,768). Applicant respectfully traverses.

Regarding claims 43-46 and 61-62:

Claims 43-46 ultimately depend on and incorporate the language of base claim 41. Claims 61-62 ultimately depend on and incorporate the language of base claim 57. However, Applicant cannot find in Schloss and/or Verboven-Nelissen any disclosure, teaching, or suggestion of delivering a pacing pulse from the left ventricle to the right atrium, as discussed above with respect to the § 103 rejection of claims 41 and 57. Accordingly, Applicant respectfully requests withdrawal of this basis of rejection of these claims.

Regarding claims 71-73:

Applicant cannot find in the cited portions of Schloss and/or Verboven-Nelissen, any disclosure, teaching, or suggestion of programming at least one first pacing pulse vector between (1) at least one of a first left ventricular electrode and a second left ventricular electrode in a left ventricular region, and (2) a right ventricular electrode in a right ventricular region, and programming at least one second pacing pulse vector between (1) at least one of the first left ventricular electrode and the second left ventricular electrode, and (2) an electrode in a right atrial region, as recited or incorporated in claim 71-73.

Also, Applicant is unable to find a suggestion of the desirability of the claimed invention in the proposed combination of references.

Accordingly, Applicant respectfully requests withdrawal of this basis of rejection of these claims.

Regarding claims 74 and 75:

Applicant cannot find in the cited portions of Schloss and/or Verboven-Nelissen any disclosure, teaching, or suggestion of, among other things, a method that includes disposing a first electrode in association with a left ventricular region of a heart, disposing a second electrode in association with a right atrial region of the heart, and delivering a first pacing pulse between the first and second electrodes, as recited or incorporated in claims 74 and 75.

Accordingly, Applicant respectfully requests withdrawal of this basis of rejection of these claims.

Conclusion

Applicant respectfully submits that the claims are in condition for allowance and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's attorney ((612) 373-6951) to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743

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CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail, in an envelope addressed to: Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 1 day of March, 2004.

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